September 21, 2021
SymBio Pharmaceuticals Limited
Fuminori Yoshida
Representative Director
President and Chief Executive Officer
(Securities Code: 4582)

Initiation of controls on shipments of TREAKISYM® lyophilized injection formulation

TOKYO, Japan, September 21, 2021 -- SymBio Pharmaceuticals Limited (Headquarters: Tokyo, "SymBio") today announced that it will initiate controls on shipments of TREAKISYM® lyophilized injection formulation ("FD") in regards to a potential stockout of FD arising from delay in converting from FD to its successor formulation, the new TREAKISYM® ready-to-dilute liquid injection formulation ("RTD").

SymBio launched RTD in January 2021 and currently markets both the RTD and FD formulations and is actively converting the market from FD to RTD.

The Company continues to ensure sufficient inventory and stable supply of RTD.

In addition, in May 2021, the Company completed the submission of the application for approval of the rapid infusion administration, TREAKISYM® RI, which has a reduced administration time.

There is no change to the Company's earnings forecast for the fiscal year ending December 2021.

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About TREAKISYM®

TREAKISYM® (non-proprietary name: bendamustine hydrochloride), a cytocide anti-cancer drug first used in Germany in the 1970s, is now widely used in more than 50 countries with indications for low-grade non-Hodgkin's lymphoma, mantle cell lymphoma, and chronic lymphocytic leukemia.

- TREAKISYM® Intravenous Infusion, freeze-dried (FD) formulation, was approved in October 2010 for manufacturing and marketing for the indication of relapsed/refractory low-grade B-cell non-Hodgkin's lymphoma and mantle cell lymphoma in Japan.
- TREAKISYM® was approved for the additional indication of chronic lymphocytic leukemia in Japan in August 2016.
- TREAKISYM® was approved for the additional indications of first-line treatment of low-grade B-cell non-Hodgkin's lymphoma and mantle cell lymphoma in Japan in December 2016.
- TREAKISYM® ready-to-dilute (RTD) liquid formulation was approved in Japan in September 2020 for all the above indications.
- TREAKISYM® FD and RTD were approved for the additional indication of relapsed or refractory DLBCL in March 2021 and April 2021, respectively.

About SymBio Pharmaceuticals Limited

SymBio Pharmaceuticals Limited was established in March 2005 by Fuminori Yoshida who previously served concurrently as Corporate VP of Amgen Inc. and founding President of Amgen Japan. In May 2016, SymBio incorporated its wholly-owned subsidiary in the U.S., SymBio Pharma USA, Inc. (Headquarters: Menlo Park, California, President: Mr. Fuminori Yoshida). SymBio's underlying corporate mission is to "deliver hope to patients in need" as it aspires to be a leading global specialty biopharmaceutical company dedicated to addressing underserved medical needs.